

From: Blobaum, Sam [Blobaum.Sam@epa.gov]
Sent: 12/1/2020 10:13:02 PM
To: Bolen, Derrick [bolen.derrick@epa.gov]; Collazo Reyes, Yvette [CollazoReyes.Yvette@epa.gov]; Dekleva, Lynn [dekleva.lynn@epa.gov]; Dennis, Allison [Dennis.Allison@epa.gov]; Drinkard, Andrea [Drinkard.Andrea@epa.gov]; Dunn, Alexandra [dunn.alexandra@epa.gov]; Fischer, David [Fischer.David@epa.gov]; Giddings, Daniel [giddings.daniel@epa.gov]; Goodis, Michael [Goodis.Michael@epa.gov]; Hanley, Mary [Hanley.Mary@epa.gov]; Hartman, Mark [Hartman.Mark@epa.gov]; Henry, Tala [Henry.Tala@epa.gov]; Hughes, Hayley [hughes.hayley@epa.gov]; Kaiser, Sven-Erik [Kaiser.Sven-Erik@epa.gov]; Keigwin, Richard [Keigwin.Richard@epa.gov]; Kochis, Daniel [Kochis.daniel@epa.gov]; Labbe, Ken [Labbe.Ken@epa.gov]; Layne, Arnold [Layne.Arnold@epa.gov]; Lieberman, Paige [Lieberman.Paige@epa.gov]; Messina, Edward [Messina.Edward@epa.gov]; Mills, Madeline [Mills.Madeline@epa.gov]; Nguyen, Khanh [Nguyen.Khanh@epa.gov]; OPS CSID CB [OPS_CSID_CB@epa.gov]; Pierce, Alison [Pierce.Alison@epa.gov]; Richmond, Jonah [Richmond.Jonah@epa.gov]; Siciliano, CarolAnn [Siciliano.CarolAnn@epa.gov]; Sullivan, Melissa [sullivan.melissa@epa.gov]; Tyler, Tom [Tyler.Tom@epa.gov]; Vendinello, Lynn [Vendinello.Lynn@epa.gov]; Vernon, Jennifer [Vernon.Jennifer@epa.gov]
Subject: OCSPP News for December 1, 2020

OCSP News Round-Up

Special News on PFAS/Solvay

- JD Supra (Mitchell, Williams, Selig, Gates & Woodyard) 11/30; [PFAS/Natural Resource Damages: New Jersey Attorney General Files Cost Recovery Action Against Gloucester County Facility](#)
- The Intercept 11/25; [CONTAMINANTS IN NEW JERSEY SOIL AND WATER ARE TOXIC, DOCUMENTS REVEAL](#)
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TSCA

- Boston Globe 12/1; [Toxic 'forever chemicals' found in pesticide used on millions of Mass. acres when spraying for mosquitoes](#)
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- Inside TSCA 11/30; [Industry Protests Inclusion Of Fetal Heart Defect Study In TCE Analysis](#)
- Inside TSCA 11/30; [EPA seeks small entity advice on TCE, CCl4 risk management rules](#)

Pesticides

- WNAX Radio 12/1; [Corn Executive Hopes Glyphosate Holds Up Under Latest EPA Review](#)
- Chemical Week 12/1; [US EPA finds that glyphosate may affect endangered species](#)
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COVID/Disinfectants

- Inside TSCA 11/30; [New EPA Pathogen Group Highlights Debate On Use Of Disinfectants](#)

Blog/OpEd/Other

- Bergeson & Campbell TSCA Blog 12/1; [Jeffery Morris, Former OPPT Director, Describes How TSCA Can Be Used to Examine Chemical Exposure Impacts on Tribal and Fenceline Populations](#)
- Bergeson & Campbell Pesticide Law and Policy Blog 12/1; [EPA Seeks Comments on Updated Draft Guidance for Pesticide Registrants on Plant Regulators and Claims, Including Plant Biostimulants](#)
- JD Supra (Beveridge & Diamond) 12/1; [EPA Releases Updated Draft Guidance for Biostimulant Products](#)

PFAS/Natural Resource Damages: New Jersey Attorney General Files Cost Recovery Action Against Gloucester County Facility

<https://www.jdsupra.com/legalnews/pfas-natural-resource-damages-new-67862/>

The New Jersey Attorney General ("AG") on behalf of the New Jersey Department of Environmental Protection filed a lawsuit in Superior Court of New Jersey Law Division ("Gloucester County") against Solvay Specialty Polymers USA, LLC ("Solvay"); Arkema Inc. ("Arkema"); and ABC Corporations 1-10 (Names Fictitious).

The Complaint and Jury Trial Demand ("Complaint") alleges that Solvay and Arkema are responsible for contamination related to per- and polyfluoroalkyl substances ("PFAS") originating from a Gloucester County facility ("Facility").

Hazardous substances, pollutants, and contaminants are alleged to have been discharged and emitted at and from the Facility which include PFAS. Further, the Complaint alleges that the current owner of the Facility (Solvay) has refused to comply with directions to investigate contamination from the Facility and pay for treatment of contaminated drinking water.

The Complaint is filed pursuant to:

- Spill Compensation and Control Act, N.J.S.A. 58:10-23.11 to -23.24
- Water Pollution Control Act, N.J.S.A. 58:10A-1 to -20
- Air Pollution Control Act, N.J.S.A. 26:2C-1 to -57
- Solid Waste Management Act, N.J.S.A. 13:1E-1 to -230.
- Brownfield and Contaminated Site Remediation Act, N.J.S.A. 58:10B-1 to -31
- Common law of New Jersey

The New Jersey Department of Environmental Protection is stated to have become aware of the PFAS allegedly released at the Facility through a study conducted by the Delaware River Basin Commission from 2007-2009. It is described as a multi-year survey of contaminants of emerging concern in the Delaware River.

The AG states that the Complaint has been brought to require Solvay and Arkema to fully investigate and delineate all of the pollutants and hazardous substances, including PFAS compounds, that allegedly were and continue to be discharged, released, and/or emitted from the Facility wherever they have come to be located.

In the alternative, the AG seeks all the costs necessary to fully investigate and delineate all the pollutants and hazardous substances, including PFAS compounds, that allegedly were and continue to be discharged, released, and/or emitted from the Facility wherever they have come to be located.

Also included is a request that both companies remediate, assess and restore the Facility and all the off-site areas and natural resources of New Jersey that have allegedly been contaminated from the Facility.

A copy of the Complaint can be downloaded [here](#).

CONTAMINANTS IN NEW JERSEY SOIL AND WATER ARE TOXIC, DOCUMENTS REVEAL

Sharon Lerner, The Intercept

<https://theintercept.com/2020/11/25/solvay-new-jersey-pfas-documents/>

DOCUMENTS MADE PUBLIC by the New Jersey Department of Environmental Protection and the U.S. Environmental Protection Agency [show](#) that PFAS compounds the chemical company Solvay has released in New Jersey are toxic to lab animals and people, stay in the human body for years, and were found in the blood of workers at two of Solvay's plants.

According to a [December 2019 letter](#) Solvay sent to the EPA, blood monitoring of workers at two of its plants between 2011 and 2019 showed that the compounds were present at high levels and had harmful effects. The same compounds have been found in [soil](#) and [private well water](#) near the company's plant in West Deptford, New Jersey.

The scientists found "positive statistical associations" between the levels of the compounds in the blood samples and liver enzymes; triglycerides, a type of fat that can increase the risk of heart disease; and FT3, a hormone produced by the thyroid. The letter also noted "potential positive statistical associations" between the compounds and PSA, or prostate-specific antigen, which is a marker for prostate cancer. Increased levels of the chemicals were associated with decreased markers of immune response, according to the letter.

Importantly, the company also revealed that the compounds stay in the body for significant amounts of time. The letter estimates the half-life of the compounds in humans — or the amount of time it takes for internal levels of the chemical to be reduced by half — to be "approximately 2.5-3 years." The compounds have been referred to as "replacements" because Solvay has continued to use them even after it phased out [PFOA](#) and PFNA, chemicals in the same industrial family that were used for similar purposes and were deemed dangerous because of their toxicity and the amount of time they lasted in the human body. But the replacements have an almost identical half-life in humans to PFNA.

Apparently, some of the chemicals, which are produced outside of the U.S., were granted "low-volume exemptions" by the EPA, a process that allows companies to begin producing or importing less than 10,000 kilograms per year of a substance without having to undergo a full safety review.

The documents also detail two studies that show the compounds cause health effects in rats. One, in which the rats were exposed to the chemicals for four weeks, showed "dose-related adverse toxic effects, some of which were not reversible up to two weeks following termination of exposure," according to a [letter](#) Solvay Solexis sent to the EPA in February 2011. The liver was the "main target," according to the letter, but other observed effects included lung toxicity and reproductive organ toxicity. The letter also noted "thymus toxicity," which can be an indication of harm to the immune system. In the second experiment, in which rats were exposed to the chemicals for 13 weeks, the scientists observed changes to the liver and thyroid glands.

In an email, a Solvay spokesperson said that the company "will phase out fluorosurfactant process aids currently in use in West Deptford in 2021." The company did not respond to a question about why it had withheld the information about its chemicals' toxicity but noted that "the information that has been released is no longer trade secret and proprietary information to Solvay."

The spokesperson also said that "Solvay is fully committed to completing the investigation and remediation of any PFAS impacts scientifically attributable to its West Deptford facility in compliance with applicable laws and regulations."

Solvay had previously withheld this information from the public on the grounds that it was "confidential business information." But after New Jersey filed suit against the company, multiple news organizations filed public records requests, and The Intercept [pointed out](#) that federal law prohibits companies from claiming such studies as confidential business information, Solvay agreed to make them public.

An international chemical company based in Brussels, Solvay has been secretive about its use of PFAS compounds. In addition to attempting to withhold information about the chemicals' health and environmental effects from the public, the company has also refused to provide the NJDEP with an analytical sample of the chemicals. These official samples are necessary for scientists to confirm the presence of the compounds in the environment, and without them, scientists have had to hedge in their language. In a June [paper](#) in the peer-reviewed journal Science, staff scientists from the EPA and the NJDEP described the contaminants as "compounds that appear to have emanated from" the Solvay plant in West Deptford. But an Italian scientist working on contamination near a Solvay plant in Italy recently shared an analytical standard of the chemicals with the EPA, which has allowed the U.S. agency to definitively identify the compounds' presence in New Jersey.

Solvay Workers Found to Have Unregulated PFAS in Their Blood, Documents Show

Ryan Felton, Consumer Reports

<https://www.consumerreports.org/toxic-chemicals-substances/solvay-workers-found-to-have-unregulated-pfas-in-their-blood-documents-show/>

Little-known chemicals used by the manufacturer Solvay Specialty Polymers as replacements for now-regulated PFAS chemicals have been detected in the blood of company workers, according to documents obtained by Consumer Reports. The documents, which include multiple internal company studies, also show that the company has known of potentially severe health risks, including liver damage, with the chemicals for at least 15 years.

Solvay's manufacturing processes have been in the spotlight for months, after researchers from the Environmental Protection Agency and New Jersey Department of Environmental Protection (NJDEP) reported finding new, potentially dangerous chemicals, first in soil samples from multiple locations in New Jersey and then in drinking water.

The researchers tentatively identified the new compounds as a "substitute PFAS" known as chloroperfluoropolyether carboxylates, or ClPFPECA, and concluded that Solvay's plant in West Deptford, N.J., was the likely source of contamination. (Solvay has denied responsibility.)

The findings inflamed concerns among consumer advocates and researchers about PFAS, a group of more than 5,000 chemicals that persist in the environment essentially forever and have been linked to learning delays in children, cancer, and other health problems.

In 2018, New Jersey set strict limits for one PFAS, called PFNA (perfluorononanoic acid), which had been used by Solvay until 2010. Solvay has since phased out PFNA, which preliminary research has linked to immune-system and liver problems.

The state sued Solvay earlier this month, alleging in part that in place of PFNA, the company has been using other related compounds at its manufacturing facility for more than two decades and polluting water supplies in the process. The state believes Solvay's replacements may be even more toxic than well-studied PFAS compounds.

"The testing results that EPA provided indicate that the new perfluoro ether compounds detected in the water and soil in New Jersey are a serious concern from a public health perspective," says David Andrews, senior scientist at the Environmental Working Group, an advocacy group, who reviewed the documents for CR.

In July, Consumer Reports filed a Freedom of Information Act request to the EPA for any toxicology reports filed by Solvay pertaining to ClPFPECA. On Tuesday, the agency turned over nine studies covering two of those compounds, dating from early 1998 through late 2019.

Solvay provided the toxicological reports to the state last year, NJDEP records obtained by CR show. The studies provide the clearest evidence to date about the potential health risk associated with the ClPFPECA family of compounds, and shows for the first time what information regulators have about the chemicals Solvay has used.

One of the reports, filed in February 2011, cited numerous health effects from one ClPFPECA in lab rats, including reproductive problems, liver damage, and lung toxicity. Companies are required to immediately notify the EPA, under the Toxic Substances Control Act, when substances "present a substantial risk or injury to health or the environment."

Industry groups claim that newer PFAS are safer and less likely to accumulate in tissue. But estimates of the company's replacements in another Solvay document, from 2019, suggest that they last as long as better-studied PFAS compounds.

"It is stunning that the replacement chemicals for PFOA and PFNA could be as bioaccumulative and toxic," Andrews says. "Unless there is other significant data that EPA has not disclosed, it seems these new compounds made it to market on nothing more than a belief that they would be safer."

In response to questions from CR, Solvay says it is phasing out the use of PFAS chemicals at its manufacturing facility in the town of West Deptford, N.J., at some point in 2021, but the company declined to answer any questions about the studies provided to the EPA.

“Solvay is fully committed to completing the investigation and remediation of any PFAS impacts scientifically attributable to its West Deptford facility, in compliance with applicable laws and regulations,” the company said in a statement. The company uses a “very limited quantity” of PFAS at the facility, the statement said.

Solvay had previously declined to release any information about the safety of the replacement PFAS. But because it will now phase the compounds out of production, the statement says, it’s no longer proprietary information.

Michael Hansen, PhD, a senior scientist at CR, says the studies demonstrated that adverse health impacts occurred from low levels of exposure to the compounds.

“Given that a study from 15 years ago, and further studies done six years later, all showed adverse effects at fairly low levels, Solvay should have made them public years ago and not have argued that the identity of this compound, as well as the toxicity studies themselves, were confidential business information,” he says.

'Clear Indication of a Toxic Effect'

In an October 1998 acute toxicity experiment, rats were given varying amounts of one CIPFPECA and observed for 14 days. Two Solvay officials, whose names were redacted, wrote in the study’s conclusion that the CIPFPECA compound “induced delayed toxicity (liver and intestine were mainly involved) in animals given the higher doses.”

Liver issues were identified again in 2005, when Solvay launched a separate four-week study on a different CIPFPECA, choosing again to administer the compound orally “as it is a possible exposure of the test item to man.” Lab rats were given three different doses of the compound daily, and found signs of toxic effects at the two higher levels.

“The findings in the liver, observed at all the doses, were a clear indication of a toxic effect of the test item to this organ,” the study said. The highest doses were also linked to decreased size of the thymus gland.

In 2011, Solvay notified the EPA about the study, which found liver issues occurred at all three levels administered. The study “should have raised major red flags at EPA,” says the EWG’s Andrews, citing the bioaccumulation and “lack of an identified dose level that did not cause harm.”

“It stands out that even weeks after dosing the rats the levels of these new compounds were so high in the rats’ blood that the researchers could not accurately predict the half-life or how long it would take for the compounds to leave their bodies,” Andrews says.

Solvay affirmed the concerns about prolonged exposure in safety data sheets it submitted to regulators in 2019 about both compounds, saying they can “cause damage to organs” through prolonged exposure.

Detected in Blood of Workers

Beyond the health effects, records obtained by CR show that Solvay has detected two CIPFPECAs in the blood of workers at two manufacturing facilities.

In a December 2019 letter to the EPA, a Solvay representative—whose name is redacted—said that analysis of worker blood samples for both CIPFPECAs began in 2011.

The company representative downplayed the findings, saying “none of these results raise concerns from a clinico-toxicological point of view, and that the overall results are not indicative of any pathological effects.”

But the letter also noted the estimated half-life of the compounds—or how long it takes for the body to break down half the chemical—in the blood of monitored workers was approximately 2.5 to 3 years, in line with levels described in a 2019 study by the Natural Resources Defense Council, an environmental nonprofit organization based in Washington, D.C.

Linda Birnbaum, a former director of the National Institute of Environmental Health Sciences and a PFAS expert, says that while PFAS chemicals do not break down in the environment, they will decrease over time in humans. And, she

says, a 2.5-year half-life is “pretty significant” because “if you’re exposed to this all the time, it’s going to build up in your body. Even if, all of the sudden, you’re no longer getting it from the outside, it’s still going to last in your body.”

The Great Unknown

An NJDEP spokesperson declined to comment, citing the pending litigation. The EPA, which regulates drinking water in the U.S., did not have an immediate comment Wednesday.

The EPA has yet to issue an enforceable limit for PFAS in drinking water, despite having been made aware of potential health effects of PFOA and PFOS, two well-studied chemicals in the group, years ago. The agency has said a process is underway to establish legal limits in drinking water for those two compounds, but they might not become enforceable for several years. To date, the EPA has provided only voluntary guidelines for PFOA and PFOS. Some states have stepped in to fill the void and have implemented legal standards for a handful of PFAS, like New Jersey did in the case with PFNA.

But the situation in New Jersey with Solvay underscores the challenges regulators will face with PFAS. When one chemical becomes regulated, companies have thousands of other, unknown chemicals at their disposal. Some advocates and researchers have called for the entire known family of PFAS to be managed as a “class,” instead of one by one.

Industry groups have dismissed the proposal as unnecessary, and the EPA has yet to weigh in on it.

Toxic ‘forever chemicals’ found in pesticide used on millions of Mass. acres when spraying for mosquitoes

David Abel, Boston Globe

<https://www.bostonglobe.com/2020/12/01/metro/toxic-forever-chemicals-found-pesticide-used-millions-mass-acres-when-spraying-mosquitos/>

For two decades, state environmental officials have used a controversial pesticide to kill mosquitoes in Massachusetts, spraying millions of acres from the air and ground to reduce the spread of Eastern equine encephalitis.

Now, after years of criticism from environmental advocates who have long raised health concerns about the expensive treatment known as Anvil 10+10, the pesticide has been found to also contain an array of toxic compounds known as PFAS. The so-called “forever chemicals,” which are found in a range of commercial products and never fully degrade, have been linked to cancer, low infant birth weights, and a range of diseases.

The amount of some of the chemicals found in the pesticide — which has been used in at least 25 other states — exceeds recent safety limits imposed by the state for drinking water. Given the amount of pesticide used, and how widely it has been dispersed over the years, specialists say it’s likely that the chemicals have leached into ground water and other water sources.

The recent findings came from a series of tests conducted this fall by the state Department of Environmental Protection, which began examining Anvil after testing by an advocacy group found similarly elevated levels of the chemicals in the pesticide.

Environmental officials said they’re trying to determine whether it’s safe to continue using the pesticide, which federal regulators have found includes other potential carcinogens. Most of the spraying has been done in the southeastern part of the state, where EEE, a rare but deadly mosquito-borne disease, has been most prevalent.

“We’re taking this very seriously,” said Dan Sieger, the state’s undersecretary for environmental affairs. “When we figure out the source of the contamination . . . we’ll make a decision.”

Officials at Clarke, the Illinois company that produces Anvil, said that no PFAS chemicals are used in the pesticide, but acknowledged the possibility they could have been introduced through manufacturing or packaging.

Mark Smith, director of the DEP’s office of research and standards, said he has been studying how the chemicals may have been dispersed and whether they present a health danger.

“The reason we’re taking this so seriously, and why we’re concerned, is that these compounds are so persistent in the environment,” he said.

Concerns about PFAS, man-made chemicals invented in the 1940s as water repellents and flame retardants, have risen as a growing body of research links long-term exposure to an array of health problems. In response, an increasing number of states have enacted stricter limits on the amount allowed in drinking water.

So far, Smith’s assessments suggest the PFAS in the pesticide haven’t “presented significant risk to water supplies, because of the dilution factor,” he said. When the chemicals are dispersed, they decline in concentration.

“I’ve done some worst-case calculations to determine what levels might land in a drinking water reservoir, and the results wouldn’t be measurable,” he said.

But he acknowledged there are unknowns, given that the pesticide has been used in large amounts for the past 20 years and the PFAS do not break down, accumulating over time.

Since September, the department has tested nine samples from five separate containers of Anvil and detected eight different compounds of PFAS. Of those, three compounds substantially exceeded the state’s new limits, in some cases by more than sevenfold. Other unregulated PFAS chemicals were detected in even greater amounts.

Officials at the US Environmental Protection Agency, which has been criticized for delaying new standards to reduce PFAS exposure, said they were looking into the findings and plan to conduct their own tests of Anvil.

“There are significant unanswered questions about the data currently available,” said Dave Deegan, a spokesman for the EPA’s offices in New England, adding that the agency is working on “an analytical method” to detect PFAS in pesticides. “EPA will continue to work closely with and support the state on this issue. Aggressively addressing PFAS continues to be an important, active, and ongoing priority for EPA.”

Last year, Massachusetts spent more than \$5 million to spray Anvil from helicopters and airplanes, dousing more than 2 million acres over 26 days in 100 municipalities. It was the state’s most deadly outbreak of EEE since the 1950s, with six deaths among the 12 people who contracted the disease.

This year, with drought conditions reducing the mosquito population, the state sprayed 200,000 acres in 23 municipalities. There have been no deaths in 2020.

State officials did not provide information about how much of the pesticide was sprayed on the ground.

Officials at Clarke defended their product and said they were awaiting guidance from regulators about how best to conduct their own tests.

“Anvil has played an important role in preserving public health for three decades,” said Karen Larson, the company’s vice president of government affairs. “Confidence in these products is critical to achieve public health goals, and we will continue to work closely with the EPA to conduct our own testing.”

Larson said it was unclear why the company’s pesticide contained PFAS.

“When this was first brought to our attention, we conducted an internal inquiry of our manufacturing and supply chain to ensure that PFAS was not an ingredient in the production, manufacturing, or distribution of either the active or inactive ingredients of Anvil,” she said.

“No PFAS ingredients are used in the formulation of Anvil, nor in the production of any source material in Anvil. PFAS components are not added at any point in the production of Anvil,” she added.

Some environmental advocates were skeptical of the company’s claims, noting that PFAS have been used in other pesticides and can extend their shelf life and help make them easier to disperse.

In a letter to DEP officials, Public Employees for Environmental Responsibility, a Washington advocacy group, noted its own tests of Anvil found the pesticide contained 250 parts per trillion of one of the chemicals regulated by the state —

more than 22 times the new limit for drinking water. They found other unregulated PFAS compounds in even greater amounts.

While Clarke doesn't list the chemicals as active ingredients of Anvil, they could be inert ingredients, they said.

"Pesticide manufacturers usually withhold information from the public about inert ingredients as 'trade secrets' or 'proprietary' information," wrote Tim Whitehouse, executive director of PEER. "Therefore, it is conceivable that PFAS are added deliberately to pesticide formulations."

Larson dismissed the possibility that PFAS were inert ingredients.

"We have reached out to the manufacturers of the active and inert ingredients, and they also confirm that PFAS is not an ingredient in the production, manufacturing, or distribution of the product's ingredients," she said.

Whitehouse noted an increasing number of municipalities in Massachusetts have detected elevated levels of PFAS in their drinking water, and that many of them are now struggling to pay for the expensive equipment designed to filter out the toxic chemicals.

As of this month, 32 of 164 public water systems tested over the past year had more PFAS in their drinking water than allowed, state officials said.

"While it is likely some of the contamination is coming from wastewater treatment plants and consumer goods, it is also possible that some of the widespread contamination is coming from Massachusetts' aerial and ground-based spraying of Anvil," wrote Whitehouse, who urged the state to stop using the pesticide or any others that contain PFAS.

Some scientists and lawmakers echoed his concerns. Laurel Schaider, a research scientist at the Silent Spring Institute in Newton, which has received large grants from the federal government to study PFAS, said she was "very concerned" about the state's findings.

She noted that some of the chemicals the state detected in Anvil are newer "short-chain" PFAS compounds, which she described as "even more mobile in the environment and more difficult to remove from drinking water."

"We already have a public health crisis in this country with PFAS contaminating drinking water, and we don't want to make the situation worse," Schaider said.

State Senator Jo Comerford, a Northampton Democrat who chairs the Legislature's Joint Committee on Public Health and is an observer on the state's newly created Mosquito Task Force, called the state's findings "significantly concerning."

With the state expecting a bad EEE season next summer — the disease usually spikes in three-year cycles — she said environmental officials should issue a moratorium on Anvil and take steps to protect the public without using such toxic chemicals.

"These findings should be a wake-up call for all of us," Comerford said.

Firefighters Fret Over Health Threats From What Protects Them

Andrew Wallender, Bloomberg Law

<https://news.bloomberglaw.com/environment-and-energy/firefighters-fret-over-health-threats-from-what-protects-them?context=search&index=2>

Firefighter Paul Cotter faced all manner of risks in his 28 years on the job—collapsing buildings, smoke inhalation, heat exhaustion, mental stress. But there was one threat he never considered: the protective garments he wore when responding to calls.

Firefighters' "bunker gear" contains significant amounts of chemicals known as PFAS, so-called "forever chemicals" that are linked a host of health problems, including prostate cancer—which Cotter battled.

“No one had ever heard of it before,” Cotter said of PFAS in gear.

Recent lawsuits and legislation have focused primarily on the alleged health risks presented by fire-suppressing foams, some of which also contain PFAS. But now, plaintiffs’ attorneys and lawmakers are increasingly looking at the gear worn by firefighters.

Elizabeth Pritzker of Pritzker Levine LLP is one of those attorneys. She’s representing two dozen firefighters in a California district court case against foam makers and manufacturers of personal protective gear worn by firefighters, including 3M Co., W.L. Gore & Associates, and Johnson Controls Inc.

The plaintiffs were all diagnosed with cancers—nine with prostate cancer like Cotter—and had PFAS in their blood well above national averages, which Pritzker called “a substantial causational link.”

“We think it’s going to bring about change in the industry, and ideally give them compensation for their injuries,” she said of her lawsuit.

The companies have all denied wrongdoing. A spokesperson for 3M said that 3M Scott Fire & Safety “uses limited quantities of certain fluoropolymers in components of firefighter protective equipment.”

“3M’s products have been tested and assessed to help assure their safety for their intended uses,” spokesperson Sean Lynch said.

Firefighters and Cancer

PFAS stands for per- and polyfluoroalkyl substances, a group of human-made chemicals that first hit the market as coatings for Teflon pans in the 1950s, and are now found in products like microwave popcorn bags, pizza boxes, carpets, and cosmetics.

PFAS include thousands of compounds, including PFOA, PFOS, and GenX. They are known for their stability and water and heat resistance, thus making them ideal for firefighter gear.

But they are also linked to increased cholesterol levels, changes in liver enzymes, lower infant birth weights, and increases in the risk of kidney or testicular cancer, according to the Centers for Disease Control and Prevention.

It was that link to cancer that led Massachusetts resident Diane Cotter, Paul’s wife, to ask University of Notre Dame professor and nuclear physicist Graham Peaslee to investigate the gear. The resulting study found firefighter textiles had “high levels of total fluorine,” a critical component of PFAS.

Students collecting garment samples for Peaslee had such alarming levels of potentially toxic fluorochemicals on their hands after handling the gear, they were required to wear gloves and take protective measures.

There’s no question there’s PFAS in the gear, Peaslee said. Now it’s a question of whether it’s getting into firefighters’ bodies and accumulating there.

Paul Cotter was diagnosed with prostate cancer in October 2014. He had no family history of cancer. He also didn’t use the PFAS-containing firefighting foams that are being scrutinized for their role in polluting local water supplies with PFAS.

He underwent surgery to remove the cancer, but the development led to an early retirement, cutting short a promotion to lieutenant that came a week before the diagnosis. It also prompted phone calls from friends and colleagues sharing their own tales of cancer battles, and confusion about the source.

“I keep the list,” Cotter said of those calls. “I have about 35 names on the list right now.”

Next Litigation Trend

Hundreds of lawsuits have already been filed against manufacturers of PFAS-containing firefighting foam.

But Pritzker's California lawsuit was one of the first to also seek damages from turnout gear manufacturers, alleging that firefighter's uniforms were leading to clusters of cancer outbreaks.

Also looking at the issue is Rob Bilott, a partner in Taft Stettinius & Hollister LLP's Cincinnati office who was portrayed in the 2019 film "Dark Waters" for his successful litigation against DuPont on behalf of West Virginia residents.

Bilott is leading a proposed nationwide class action out of Ohio whose lead plaintiff, Kevin Hardwick, is a firefighter alleging he's been exposed to high levels of PFAS through his job.

Notably, the case mentions Hardwick's exposure to gear "treated and/or coated with materials containing and/or contaminated with one or more PFAS materials."

Lawyers bringing the proposed class action, which has survived several motions to dismiss, want a court to force the companies to study the effects of PFAS on the human body. They also want to compel the creation of an independent PFAS science panel funded by the manufacturers.

New Research Coming

Manufacturers caution that some substances found in firefighter gear are "polymers of low concern" that shouldn't be looped in with other PFAS.

These fluoropolymers, which include PTFE, have high molecular weights incapable of crossing cell membranes, don't bioaccumulate, and are insoluble in water, according to Amy Calhoun, a spokesperson for W.L. Gore & Associates. The company manufactures components that go into turnout gear.

"Our commitment is clearly to the health and safety of the firefighters," Calhoun said, and making sure their product meets required standards.

At least three other studies—including two federally funded projects—are ongoing to determine the presence of PFAS in turnout gear, how easily it may shed from the gear, and its ability to enter firefighters' bodies.

"There's a lot of PFAS chemicals out there, and there are many that we really don't know what effects they have," said University of Arizona researcher Jefferey Burgess, who is leading one of the two federally funded studies.

The International Association of Fire Fighters—the country's largest firefighting union—is also working on gathering research on the safety risks of PFAS, said spokesperson Doug Stern. The union is involved in three studies looking at PFAS levels in firefighters' blood, PFAS levels in the dust of fire houses, and PFAS levels in turnout gear.

"It's definitely something that's a high priority for the IAFF—to look into this and determine whether or not PFAS levels in firefighting gear have a direct correlation to firefighters' occupational cancer," Stern said.

'Burn to Death'

The chemical industry has resisted efforts to ban PFAS in firefighting gear, said Bill Allayaud, the Environmental Working Group's director of California government affairs, who worked on a recent California law that bans the toxic fluorinated chemicals in firefighting foams.

Tom Flanagan, a spokesman for the American Chemistry Council, said "we do have concerns that restricting PFAS in firefighter turnout gear could put the lives of our first responders in jeopardy."

Improper turnout gear "can mean the difference between life and death, not just for the firefighter but also for potential fire victims. Despite years of research into potential alternatives, which is ongoing, use of PFAS-based materials remains the only viable option," he said.

Several states, including California, Minnesota, Kentucky, and Virginia, have begun to regulate PFAS in firefighting foam—but efforts to regulate turnout gear are just beginning. Without good alternatives to PFAS-free turnout gear, lawmakers are crafting and passing legislation that at least mandates gear makers disclose the dangers of exposure to PFAS.

California state Sen. Ben Allen (D) successfully pushed legislation that bans the toxic chemicals from firefighting foams, which Gov. Gavin Newsom (D) signed in September.

There is also a notification requirement of the hazards of chemicals in turnout gear—similar to provisions in recently passed laws in New York, Washington, Colorado, and New Hampshire—that “makes firefighters aware of the chemicals and the risks of them. We want people to be more cognizant of that,” Allen told Bloomberg Law.

“No state has actually banned it in the PPE because at least up until now there hasn’t been a viable alternative,” he said, referring to personal protective equipment. “As much as a firefighter doesn’t want to get cancer 20 years from now, they don’t want to burn to death five seconds from now.”

PFAS or Nothing

But getting PFAS out of gear is next to impossible, said fire prevention officer Sean Mitchell of the Nantucket, Mass., Fire Department.

Mitchell went on the hunt for PFAS-free gear earlier this year after his department received funding to replace older uniforms. He called manufacturing representatives and read research. Several months later, he still hasn’t made a purchase. “There’s nothing out there,” Mitchell said.

The problem is twofold. PFAS presents itself in the water-resistant outer layer of uniforms, as well as the inner moisture barrier that improves garment breathability and provides an additional barrier against fluids.

PFAS-free outer layers are in development and scheduled for sale next year, including a product called PF Zero by manufacturer Safety Components.

But the inner moisture barrier presents complications. Only moisture barriers made with PFAS can meet minimum safety certifications established by the National Fire Protection Association, or NFPA. At issue is a provision—Section 8.62 of NFPA 1971—added in 2007 to the NFPA’s standards for structural firefighting gear. It requires moisture barriers to be able to withstand “40 hours of continuous light exposure.”

The only products on the market that can meet that UV exposure requirement contain Teflon, which uses PFAS in the production process, according to Peaslee. He said the UV test requirement “makes absolutely no sense.”

“I could imagine it being a test on the outside,” Peaslee said. But “they only do it on the inside liner, on the part that never sees sunlight.”

Blowback From Firefighters

Cotter, the long-time Massachusetts firefighter, is now cancer-free. But insisting firefighting gear could be dangerous led to clashes between the Cotters and the IAFF, as well as its affiliated Professional Fire Fighters of Massachusetts. Diane Cotter said many in union leadership won’t talk to them, a development Paul called “devastating.”

Stern, the IAFF spokesperson, denied any efforts to shun the couple, and said the union shares the same goals as the pair but “two different paths to get there,” with the union awaiting further research results.

Professional Fire Fighters of Massachusetts President Richard MacKinnon said his association is also committed to awaiting further studies linking PFAS in gear to cancer, and using the legislative process to enact change.

“I think they’re well-intentioned,” MacKinnon said of the Cotters. “But again, some of their efforts have been contradictory to us.”

Despite disagreements in process, Paul Cotter said he’s encouraged by departments changing how they handle protective clothing as they await PFAS-free alternatives.

“We just need more people to know about it and to demand change,” Cotter said. “We can change it. We can make the fire service a little bit safer.”

Industry Protests Inclusion Of Fetal Heart Defect Study In TCE Analysis

Maria Hegstad, Inside TSCA

<https://insideepa.com/tsca-news/industry-protests-inclusion-fetal-heart-defect-study-tce-analysis>

The chemical industry is protesting EPA's references to a study on fetal heart defects from exposure to trichloroethylene (TCE) in its recently issued final TSCA risk evaluation of the widely used solvent, despite the agency's use of a less-sensitive health endpoint in its unreasonable risk findings.

In a Nov. 24 statement, the American Chemistry Council (ACC) argued the 2003 study, by Paula Johnson at the University of Arizona and colleagues, has been discredited and should not be cited. "With the release of the final risk evaluation for [TCE], [EPA] has not gone far enough in invalidating the purported risk of fetal cardiac defects (FCDs), which is not supported by the vast majority of available research," ACC charged.

"The agency continues to reference and validate a 2003 study about FCDs, which its own advisory panel largely rejected earlier in the year due to scientific flaws in how it was conducted and results that have not been replicated in subsequent studies," according to ACC.

The group says that even though EPA based its overall risk estimate for non-cancer effects of exposure to TCE on immune system effects rather than the more-sensitive FCDs identified in the Johnson study, it is still concerned that its inclusion of the Johnson study could leave the door open to addressing risks of FCD when EPA writes risk management rules in the future.

At issue is EPA's Nov. 23 [final TCE risk evaluation](#), which identified dozens of uses of TCE as posing "unreasonable risks" that must be addressed under the Toxic Substances Control Act (TSCA).

EPA's decision is not surprising after the agency foreshadowed this conclusion in its draft evaluation last February, which included nearly identical language explaining why the agency has chosen not to use FCDs as the basis for its risk conclusions.

The agency's decision was backed by [several members](#) of EPA's Science Advisory Committee on Chemicals (SACC), who acknowledged criticisms that the findings of the Johnson study are too uncertain to form the basis for regulatory decisions. Others, however, called for its use.

As a result, SACC was unable to reach consensus on what to recommend that EPA do with the fetal heart malformation endpoint. Instead, the committee called on EPA to provide a better justification of its decision to decline to use the Johnson study.

"The Committee agreed that the heart malformations could be used for hazard identification, although the Committee remained divided about the use of these data for risk characterization," SACC said in its report on the draft evaluation.

Despite the SACC's support, the agency's decision to drop its use of the Johnson study as the basis for its risk finding reversed EPA's last evaluation of TCE, conducted by the Integrated Risk Information System (IRIS) in EPA's research office in 2011, which based its stringent risk estimate on fetal heart effects. This resulted in a very stringent, and as a result a highly controversial, risk estimate that EPA and others have struggled to implement in the field.

Press reports attributed the change to orders by Nancy Beck, a former top Trump EPA toxics official and former ACC official who has been serving at the White House.

Unreasonable Risks

While the agency selected adverse immune effects as the basis for its non-cancer risk finding, its final TCE evaluation concludes that 52 of 54 evaluated uses of the chemical pose unreasonable risk that the agency must regulate under TSCA.

ACC does not address these findings in its statement, focusing solely on EPA's inclusion of the Johnson study. ACC argues that "[n]umerous SACC members called the Johnson study an outlier, not scientifically sound, and not fit to be included or referenced in the final risk evaluation."

EPA references SACC's advice in its final evaluation to explain its decision not to base the overall TCE risk estimate on the fetal effect, suggesting that its selection of the immune health effects instead "for use in risk conclusions was supported by the SACC peer review panel."

EPA states that it performed a "thorough" weight of evidence (WOE) analysis of the evidence regarding congenital heart defects, adding that the Johnson study is not backed up with other toxicological studies but is supported by other types of evidence, including human epidemiology studies.

"There is medium confidence in the relevance of the endpoint to human toxicity based on the results of the WOE," EPA states, before pointing out remaining uncertainty due to study design issues and the lack of corroboration "by results of other animal studies with similar quantitative results. . . . EPA does not dismiss the results of (Johnson et al., 2003), however the aforementioned uncertainties reduce confidence in that value. Nonetheless, epidemiological, metabolic, and mechanistic data suggest that congenital heart defects may be of concern for particular biologically susceptible [Potentially Exposed or Susceptible Subpopulations (PESS)] groups such as older mothers."

ACC argues that EPA should not reference the Johnson study at all. "We appreciate the fact that the EPA followed the SACC's advice and did not use Johnson's endpoint in its final evaluation, but we remain disappointed that the agency continues to reference the study," the statement says.

Specifically, ACC argues that EPA, despite SACC's cautious advice, "included the unreliable FCD-based toxicity value for future consideration of sensitive subpopulations. In effect, by maintaining the FCD-based toxicity value in the final risk evaluation, EPA has contradicted its previous decision to reject this endpoint as a basis for regulatory decision making."

An ACC spokesman points to a value in the middle of the 800-page document, in a table where EPA provides initial risk calculations for a half-dozen "most sensitive endpoints from each health domain for risk estimation of chronic exposure scenarios," including calculations based on both the Johnson study and the immune effect study EPA has based its overall estimate upon.

In its statutorily required discussion of PESS, EPA references the potential for fetal cardiac malformations as an example of a lifestage-specific susceptible population to TCE exposure.

"There is some evidence that certain populations may be more biologically susceptible to exposure to TCE. Factors affecting biological susceptibility examined in the available studies on TCE include lifestage, sex, genetic polymorphisms, race/ethnicity, preexisting health status, lifestyle factors, and nutrition status. Factors that affect early lifestage susceptibility include exposures during gestation, such as transplacental transfer, and during infancy, such as breast milk ingestion (a breastfeeding infant who is nursing from a mother exposed to the occupational exposure limit for TCE could receive more than 80% of the daily lifetime advisory limit for adults (Beamer et al., 2012)), early lifestage-specific toxicokinetics, and early lifestage-specific health outcomes including developmental cardiac defects," EPA's final evaluation states.

EPA adds that "Among life stages, the most susceptible is likely to be pregnant women and their developing fetus based on the hazard findings from reviewing the reasonably available literature for this assessment, which conclude that developmental toxicity is among the most sensitive acute health effects associated with TCE exposure. Among pregnant women, older women may be especially susceptible to TCE-induced cardiac defects in their offspring. Maternal age is known to have a large influence on the incidence of congenital heart defects, and multiple studies cited in this Risk Evaluation identified a significantly stronger association of TCE with developmental cardiac defects (Brender et al., 2014; 5317 Yauck et al., 2004)."

EPA seeks small entity advice on TCE, CCl4 risk management rules

Inside TSCA

EPA is seeking nominations from small entity representatives to advise the agency on how to craft its pending TSCA risk management rules to address the unreasonable risks the agency identified in its final evaluations of trichloroethylene (TCE) and carbon tetrachloride (CCl₄) while reducing adverse effects on small businesses.

EPA Nov. 30 issued its call for representatives from groups, including owners or operators of small businesses, small organization officials, or small-government officials to provide information and recommendations to a pair of Small Business Advocacy Review (SBAR) panels it will form, one for each chemical, as required by the Regulatory Flexibility Act.

By statute, the SBAR panels must be created for any rulemaking that may affect small businesses. They include representatives of EPA, the Small Business Administration and the White House Office of Management and Budget (OMB).

Each SBAR panel “will focus on the agency’s development of proposed rules to address unreasonable risks identified in EPA’s recently completed Toxic Substances Control Act (TSCA) risk evaluations for these chemicals,” EPA’s announcement states.

EPA is asking for nominations to be submitted by Dec. 14.

Unlike earlier calls for small entity nominations to advise SBAR panels for the first three finalized TSCA risk evaluations following Congress’ 2016 reform of the Toxic Substances Control Act (TSCA), EPA’s Nov. 30 call precedes public meetings on the evaluation and potential regulatory options. EPA has scheduled its public webinar on the CCl₄ evaluation and resulting risk management rule for Dec. 10, following a Dec. 4 roundtable on the same topics.

EPA on Nov. 23 released its [final evaluation of TCE](#) finding that 52 of 54 evaluated uses of the chemical pose unreasonable risk that the agency must regulate.

EPA released its [final evaluation](#) of CCl₄, a solvent and feedstock used to produce a host of other chemicals, on Nov. 3. The final version finds that 13 of 15 conditions of use the agency evaluated pose unreasonable workplace risks that must be regulated, including domestic manufacturing, importation, processing, recycling, multiple industrial and commercial uses as well as disposal. Those findings represent a change from the draft version, which identified only four uses that pose such risks. EPA says the unreasonable risks include cancer and liver toxicity from chronic exposures.

Corn Executive Hopes Glyphosate Holds Up Under Latest EPA Review

WNAX Radio

<https://wnax.com/news/180081-corn-executive-hopes-glyphosate-holds-up-under-latest-epa-review/>

The Environmental Protection Agency is reviewing the pesticide, glyphosate with a draft biological evaluation. That evaluation scrutinizes glyphosate’s potential effect on federally listed endangered species and designated critical habitats. Kelly Brunkhorst, Executive Director of the Nebraska Corn Grower’s Association and Corn Board says glyphosate has been used for decades and proved to be a safe and effective product.

Part of the EPA’s glyphosate concerns center around runoff and spray drift. Brunkhorst says with proper conservation practices, producers have addressed any runoff issues with glyphosate.

He says there’s a three step process used in order to ensure glyphosate can be used safely.

The recent evaluation draft put out by the EPA means that glyphosate will have to undergo more reviews before its routine registration review can be completed, likely in 2021.

US EPA finds that glyphosate may affect endangered species

Sanjiv Rana, Chemical Week

<https://chemweek.com/CW/Document/115739/US-EPA-finds-that-glyphosate-may-affect-endangered-species/goBackToCWLAT>

A new draft biological evaluation from the US EPA finds that the herbicide, glyphosate, “is likely to adversely affect a significant percent of endangered species and critical habitats”. The draft assessment, which has been issued for a 60-day public comment period, is the next step in the EPA’s ongoing regulatory review of the active ingredient. In January, the EPA reaffirmed its view that glyphosate is not a carcinogen and finalised its decision to reregister the ai. That decision was immediately challenged by lawsuits from environmentalist and farmworker groups.

Biological evaluations are the beginning of the EPA’s consultation process under the Endangered Species Act, where the Agency determines whether a pesticide may affect one or more individuals of a listed species and their designated critical habitats. The EPA will finalise the glyphosate evaluation after the public comment period. If it decides that the ai may affect a listed species or its critical habitat, it will consult with the US Fish and Wildlife Service and the National Marine Fisheries Service. Their conclusions could lead to proposals for either generic or geographically specific use restrictions on the herbicide if these are considered necessary to prevent harm to listed species or habits.

Glyphosate is used on about 298 million acres (121 million ha) of agricultural crop land every year in the US, and is effective and affordable, the EPA notes.

EPA Draft Report Finds Glyphosate Harms Many Endangered Species

Dan Nosowitz, Modern Farmer

<https://modernfarmer.com/2020/12/epa-draft-report-finds-that-glyphosate-harms-many-endangered-species/>

Much of the debate over glyphosate, the herbicide from Bayer-Monsanto, has revolved around its effects on human health.

While Bayer-Monsanto will be paying billions of dollars to settle thousands of cases alleging that glyphosate causes cancer, the news lately is not about humans—it’s about animals and their habitats. The Environmental Protection Agency this week released a draft of its findings on how glyphosate affects endangered or otherwise at-risk animals, plants, and their habitats. Those findings are not great, if you’re a fan of glyphosate.

While the EPA has maintained that glyphosate is, when used according to its label, not carcinogenic, the agency has been working on figuring out whether glyphosate is dangerous to plants and animals for months. The EPA updated how it does this analysis earlier this year, using data to indicate how a pesticide is actually used, rather than based on how the label says it should be used.

These new findings say that glyphosate, when combined with common surfactants (which help the herbicide coat leaves more evenly), is “likely to adversely affect” a whopping 93 percent of the plants and animals it examined. As for habitats that serve as homes for these at-risk plants and animals, the findings say that glyphosate is likely to have a negative effect on 96 percent of them.

Chronic exposure to glyphosate, finds the report, can inhibit a vital enzyme in many plants, without which they can experience cell death. For animals, chronic and acute exposure (exposure over an extended period of time, or a lot all at once) can result in reduced body and organ weights.

Glyphosate is one of the world’s most popular herbicides; around 280 million pounds of it are used on agricultural land, mostly corn, soy, and cotton. But a further 21 million pounds are used for non-agricultural reasons; you can find it at Home Depot, and it’s pretty popular for landscaping and home gardening.

If the report goes through the comment period as written, the EPA would have to work with other agencies, like the Fish and Wildlife Service and the National Marine Fisheries Service, to come up with a plan for protection measures. Those might include limiting glyphosate’s use in certain areas, or general limitations on its use.

New EPA Pathogen Group Highlights Debate On Use Of Disinfectants

<https://insideepa.com/tsca-news/new-epa-pathogen-group-highlights-debate-use-disinfectants>

EPA's recent creation of an advisory workgroup to weigh the lessons learned from its first-time deployment of its Emerging Viral Pathogens guidance to address the coronavirus is highlighting the growing debate over the use and effectiveness of chemical disinfectants to mitigate the spread of the disease.

Environmentalists say the Pesticide Program Dialogue Committee's (PPDC) recently created Emerging Pathogens Workgroup will not consider "fundamental flaws" in the agency's continued focus on surface disinfectants, rather than addressing more likely airborne transmission or the root causes of the pandemic.

EPA could "be much more ambitious and much more proactive than just figuring out how to approve more chemicals with pesticidal action," Lori Burd, a senior attorney at the Center for Biological Diversity (CBD) and a PPDC member, tells *Inside TSCA* in an interview.

But chemical industry officials, who suggested the creation of the workgroup, say that the agency has to ensure continued widespread production and use of such products.

"As we've seen this year, antimicrobial products are critical in the fight against disease-causing viruses, and it is essential that manufacturers are able to produce and distribute the products that combat the spread of these pathogens," Komal Jain, executive director of the American Chemistry Council's (ACC) Center for Biocides Chemistries (CBC) and a co-chair of the new workgroup, said in a Nov. 10 statement.

Such divergent views were sparked by PPDC's approval at its Oct. 28-29 meeting of its Emerging Pathogens Workgroup, which is based on a June 2020 proposal from Jain, she said in her statement.

The workgroup will consider whether and how to change its Emerging Viral Pathogens guidance after its first-time deployment of the document earlier this year.

The guidance, crafted by the Obama administration in 2016, details the agency's process for identifying effective disinfectants for use against emerging viral pathogens, such as SARS-CoV-2, and to allow registrants to make limited claims of their product's efficacy against such pathogens, according to EPA.

It outlines a voluntary, two-stage process for amending labels on certain existing products but is only available after the Centers for Disease Control and Prevention (CDC) has identified the emerging pathogen and recommended environmental surface disinfection to help control its spread.

Since EPA activated the guidance earlier this year, the agency has taken a series of additional steps to ensure supply and speed approval of disinfectants to mitigate the virus's spread.

For example, EPA last month issued interim guidance that seeks to cut the time it takes to review certain new and amended disinfectant product formulations that can provide longer-lasting benefits in curbing the virus' spread.

The agency has also sought to bolster its List N directory of products proven effective against either SARS-CoV-2 or tougher-to-kill viruses, as well as speeding research into products with residual disinfectant properties that repel viruses from a surface between cleanings.

Guidance Modifications

But according to Dr. Tajah Blackburn, senior scientist in the antimicrobial division of EPA's Office of Pesticide Programs (OPP), who will also co-chair the group, the workgroup is expected to consider changes to the guidance that could further ease approval of disinfectants.

The workgroup will consider "what lessons learned can be drawn from inaugural use [of the guidance] for the COVID-19 pandemic? Should any modifications to the guidance be considered based on these lessons learned?" according to Blackburn's slides presented at the meeting.

“Examples may be a single contact time for the most difficult to kill microorganism, standardized use directions (locations, clear, easy-to-follow) across all products, or expansion of the guidance for other microorganisms.

An EPA spokesman says the workgroup “is focused on gathering insights from this experience, including strengths, weaknesses, and any necessary modifications to the guidance.”

But CBD’s Burd says that despite the opportunity for the workgroup’s charge questions to probe into the agency’s handling of the pandemic, she isn’t hopeful that it will address her concerns.

She says OPP’s focus is on products, particularly its List N database of disinfectants that it has certified as being effective against the coronavirus or tougher-to-kill viruses, rather than addressing the issue systemically.

“EPA’s approach is ‘how can chemicals be the answer to a problem,’ not ‘how can we solve the problem,’ ‘how can we prevent the problem?’ It’s always ‘industry is pushing products, and we’ll approve products,’” Burd says. “I do think there will be good people in that workgroup, and I hope they make it as good as possible. I’m just so cynical about how [EPA approaches] issues fundamentally.”

While no PPDC members -- other than Jain -- have yet been selected for the workgroup, Burd says she is not planning to join.

“I think I don’t think I have anything to contribute to the workgroup as it’s set up because I think the fundamental premise of how they’re approaching the work, and how OPP approaches the problem, is faulty,” Burd said. “So I would just continue to raise that issue. And it seemed that they had already set their minds to having this workgroup.”

Instead, she is urging OPP to pressure other offices at the agency to adopt a systemic approach, and hopes that advocates for populations vulnerable to the coronavirus will volunteer for the workgroup.

“This office could choose to be a leader, and could say ‘we need more innovation, we need to talk about ways to approach these problems that aren’t just adding to the toxic load in the environment,’” Burd tells *Inside TSCA*. “And we’ve seen all these studies come out that increased air pollution increases severity of COVID symptoms, the folks who regulate pollution absolutely have a significant role in both stopping the next epidemic and reducing its severity.”

Burd’s concerns echo those raised by other environmentalists who have also faulted EPA’s focus on approving surface disinfectants rather than on addressing airborne transmission.

“EPA’s job is to review these materials, but the way they have pushed what they’re doing has made the focus on using a toxic chemical on all these surfaces, as opposed to what I think is the more urgent problem of dealing with ventilation and airflow in buildings,” Terry Shistar, a science advisor and board member of Beyond Pesticides, told *Inside TSCA* in a recent interview.

But a group of GOP lawmakers has been pressing the CDC to follow EPA’s approach to ensure medical professionals have access to disinfectants to address soaring demand.

“We urge the CDC to develop guidance to help clinicians know what to do when surface disinfectants are not readily available. And we hope such guidance will address whether and how surface disinfectants that the EPA is allowing for temporary emergency use can be leveraged in health care settings,” the lawmakers wrote in an Oct. 23 letter distributed by the American Dental Association.

Jeffery Morris, Former OPPT Director, Describes How TSCA Can Be Used to Examine Chemical Exposure Impacts on Tribal and Fenceline Populations

Lynn L. Bergeson, B&C TSCA Blog

<http://www.tscablog.com/entry/jeffery-morris-former-oppt-director-describes-how-tsca-can-be-used-to-exami>

On November 30, 2020, Bloomberg Law *Environment & Energy Report* published a Practitioner Insight column entitled “The Toxic Substances Control Act Under Biden: Impact on Tribal, Fenceline Populations” by Jeffery Morris, former

Director of the U.S. Environmental Protection Agency's (EPA) Office of Pollution Prevention and Toxics (OPPT) and founder of Jeff Morris Solutions LLC. Morris examines how the Biden Administration could apply the Toxic Substances Control Act's (TSCA) requirement to consider impacts on subpopulations in the evaluation of chemical risks. Morris notes that fence-line communities and American Indian and Alaskan Natives (referred to as "tribes" in the article, "recognizing that not all native people are in federally recognized tribes") have faced significant impacts from chemical exposure and should be priorities.

EPA Seeks Comments on Updated Draft Guidance for Pesticide Registrants on Plant Regulators and Claims, Including Plant Biostimulants

Lisa M. Campbell, Lisa R. Burchi, and Barbara A. Christianson, B & C Pesticide Law and Policy Blog

<http://pesticideblog.lawbc.com/entry/epa-seeks-comments-on-updated-draft-guidance-for-pesticide-registrants-on-p>

On November 30, 2020, the U.S. Environmental Protection Agency (EPA) announced the availability of, and requested comments on, the updated Draft Guidance for Plant Regulator Products and Claims, Including Plant Biostimulants (Draft Guidance). 85 Fed. Reg. 76562. The original Draft Guidance (2019 Draft Guidance) was made available on March 25, 2019. EPA states that the updated Draft Guidance "incorporates diverse and helpful changes made in response to stakeholder feedback" received during the initial comment period in 2019 and "clarifies which biostimulants, biological substances, and mixtures, in addition to the associated product label claims, EPA considers plant regulators."

EPA is now seeking comments on those changes. Comments on the updated Draft Guidance are due on or before December 30, 2020, in docket EPA-HQ-OPP-2018-0258. EPA states that it anticipates issuing the Draft Guidance in final form in January 2021.

Updates to the Draft Guidance

EPA made several changes to the Draft Guidance. Of note, the Disclaimer section of the Draft Guidance EPA now states that the "contents of this document do not have the force and effect of law and are not meant to bind the public in any way." It states further that the "document is intended only to provide clarity to the public regarding existing requirements under the law or agency policies."

Additional changes of interest to the updated Draft Guidance include:

- ***Revised Definitions of "Plant Biostimulant"***: In the 2019 Draft Guidance, EPA sought comments on whether it should develop, through rulemaking procedures, a definition for plant biostimulant. EPA states that subsequent to the release of the 2019 Draft Guidance, the U.S. Department of Agriculture (USDA) issued a Report to Congress on Plant Biostimulants that included two new definitions of plant biostimulants. As a result, EPA states that it does not plan to develop a separate definition of plant biostimulants. In the Draft Guidance, EPA deleted the Proposed European Commission definition of plant biostimulant and added two of USDA's new definitions of plant biostimulants:
 - **2019 USDA Report Alternative Definition 1**: A plant biostimulant is a naturally-occurring substance, its synthetically derived equivalent, or a microbe that is used for the purpose of stimulating natural processes in plants or in the soil in order to, among other things: improve nutrient and/or water use efficiency by plants, help plants tolerate abiotic stress, or improve characteristics of the soil as a medium for plant growth. The characteristics may be physical, chemical, and/or biological. The plant biostimulant may be used either by itself or in combination with other substances or microbes for this purpose.
 - **2019 USDA Report Alternative Definition 2**: A plant biostimulant is a substance(s), microorganism(s), or mixtures thereof, that, when applied to seeds, plants, the rhizosphere, soil or other growth media, act to support a plant's natural nutrition processes independently of the biostimulant's nutrient content. The plant biostimulant thereby improves nutrient availability, uptake or use efficiency, tolerance to abiotic stress, and consequent growth, development, quality or yield.

- **Clarification of Focus on Pesticide Claims and Composition:** In the section “Pesticide Products Required to be Registered,” EPA has added the following paragraph:

The Agency historically has had a claims-based approach to pesticide regulation, but emphasizes that the term “claims-based” does not mean “claims-only based.” As the Agency has explained, “...the term “pesticide product” will be used to describe a particular pesticide in the form in which it is (or will be) registered and marketed, including the product’s composition, packaging and labeling.” (49 FR 37917, September 26, 1984.) The Agency has always considered the composition of a product, as well as its associated claims, when making a regulatory determination, which is reflected in 40 CFR 152.15.

In the “Claims Examples” section, EPA further adds the following sentences:

When claims for increased or decreased growth, yield, germination, maturation, etc. are consequent to intended uses of products or substances as plant nutrients (fertilizers), plant inoculants, soil amendments, and/or as other non-pesticidal uses, such products and substances may be excluded from regulation under FIFRA in the absence of any plant regulator claims. The example claims listed in Tables 1a through 1c are specifically tied to the exclusions from the FIFRA definition of a plant regulator and are worded as such. When such claims for accelerating or retarding the rate of growth, or maturation, the behavior of plants, or the produce thereof are made without qualification or reference to a specific exclusion, such claims are and will continue to be considered plant regulator claims.

- **Revisions to Claim Examples:** EPA has modified the examples of plant nutrition, plant inoculant, soil amendment, generic non-pesticidal, and pesticidal claims as set forth in Tables 1a, 1b, 1c, 2, and 3. Some of the changes move a claim from one chart to another. EPA has added that certain claims can improve foliar and seed nutrient conditions. Perhaps most importantly, EPA has added a footnote to each chart that the stated examples “are not comprehensive and other claims may include other synonymous terms and phrases.”
- **Discussion of Plant Regulator Active Ingredients:** EPA has deleted what was Table 4 in the 2019 Draft Guidance, which provided a list of active ingredients contained in EPA registered products having modes of action that trigger regulation under FIFRA as a pesticide. Instead, EPA has added three new sections:
 - **Substances that have no other use than as plant regulators or pesticides:** EPA has identified certain substances that “are generally recognized to have no other significant commercially valuable use, either alone or in combination with other substances, other than use as plant regulators (i.e., as pesticides).” These include corn glutens; L-glutamic acid (LGA) and gamma-aminobutyric acid (GABA); homobrassinolide and other brassinosteroids; lysophosphatidylethanolamine (LPE); 1-Octanol; and sodium o-nitrophenolate, sodium p-nitrophenolate, and sodium guaiacolate.
 - **Substances that may have plant regulator and non-plant regulator activity:** EPA has identified “substances with additional modes of action, not considered to be plant regulator modes of action that may include, but are not limited to: the alleviation of abiotic stressors (e.g., temperature and water stress); increased water and nutrient use efficiency and/or uptake; increased availability of inorganic nutrients in the soil to plant roots and seeds; increased absorption of inorganic nutrients applied to plant foliage; and changes to the biotic and abiotic characteristics of soils making them a better medium for plant growth.” Those described by EPA include complex polymeric polyhydroxy acids (CPPAs) and humic acids (HAs); and seaweed extracts (SWE).
 - **Regulatory approaches for substances and products that have multiple plant regulator and non-plant regulator modes of action:** The Draft Guidance now states the following:

The Agency recognizes that CPPA, humic acids, seaweed extracts and other PBS products may possess multiple modes of action that are occurring simultaneously when applied to plant foliage, roots, seeds, other propagules, and to the soil. The Agency also recognizes that not all uses of PBS may be intended for plant regulator or other pest control purposes. If it can be demonstrated that a particular product has the activity claimed on the product label (and any other informational media) and does not make any plant regulator or pest control claims on the product label (and any

other informational media) it may be excluded from FIFRA regulation. Pursuant to 40 CFR 152.15(b), the Agency will consider whether a substance “has no significant commercially valuable use” other than as a pesticide, when considering whether the substance (or product) is a pesticide. If it can be demonstrated that the substances contained in such products may have significant commercially valuable uses other than as plant regulators (i.e., pesticides), they may be excluded from regulation under FIFRA in the absence of any plant regulator claims (see examples in Table 3) and in the absence of any other pesticidal claims (e.g., anti-plant pathogen claims). Review of such “multiple use” products may be conducted by the Agency under PRIA Code M009.

For example, if a product containing seaweed extracts or humic acids is intended for use in alleviating abiotic stress (e.g., extreme temperature, drought/salt stress) on plants, or for stimulating increased nutrient assimilation from the soil, is labeled using product claim examples (Tables 1a-c and 2), and can provide product performance data supporting such product claims, the product may be excluded from regulation under FIFRA.

Commentary

The removal of Table 4 from the Draft Guidance appears to address comments submitted on the 2019 Draft Guidance that criticized EPA for developing a list of active ingredients that would trigger pesticide registration requirements when several of those substances possessed non-pesticidal modes of action. Interestingly, many of the significant proposed changes address issues related to composition and to substances and products with plant regulator and non-plant regulator modes of action, rather than claims. Also of note is EPA’s current intent not to initiate a rulemaking to define plant biostimulant, but instead to rely upon definitions developed by USDA and under review by Congress.

There are a significant number of issues of interest, and those with potentially affected products should review the updated guidance closely.

EPA Releases Updated Draft Guidance for Biostimulant Products

Beveridge & Diamond PC

<https://www.jdsupra.com/legalnews/epa-releases-updated-draft-guidance-for-38024/>

Key Takeaways

- **What Happened:** EPA issued revised draft guidance clarifying the types of plant biostimulant products and claims about such products that trigger regulation under FIFRA.
- **Who’s Impacted:** Companies who produce, distribute, and/or sell plant biostimulant products.
- **What Should They Consider Doing in Response:** Review the draft guidance document – in particular the tables of claims – and assess how EPA may view their biostimulant products and associated marketing strategies. EPA has also indicated that stakeholders and any other members of the public will have a 30-day opportunity to submit comments on the draft guidance, ending on Thursday December 30, 2020.

In an updated draft guidance document released for public review on November 24, 2020 and published in the Federal Register on November 30, the U.S. Environmental Protection Agency (EPA) has revised key aspects of its earlier effort to identify the types of plant biostimulant products that are subject to regulation under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). The updated guidance builds upon and responds to public comments EPA received on the Agency’s initial draft guidance, issued in March 2019. Consistent with its earlier approach, EPA again declined to propose its own definition of a “plant biostimulant,” which is not a defined term under FIFRA or any other federal statute. Still, the updated draft guidance does provide some additional clarity as to EPA’s position on the applicability of existing FIFRA requirements to this officially undefined – but continually evolving and growing – category of popular agricultural products.

Are plant biostimulants regulated under FIFRA?

Plant biostimulant products generally refer to biochemical, microbial, or chemical substances that are intended to increase crop yields by physiologically “stimulating” the plant. In contrast to fertilizers, which provide nutrients to plants, plant biostimulants alter the way plants respond to nutrients. Critically, there has been longstanding uncertainty as to when plant biostimulants may be subject to regulation as pesticides under FIFRA.

FIFRA defines the term “pesticide” to include not only those substances that are intended to “prevent, destroy, repel, or mitigate” pests, but also a wide range of other products such as defoliants, desiccants, nitrogen stabilizers, and plant growth regulators (PGRs). See FIFRA sec. 2(u). In turn, a PGR is defined to mean “any substance or mixture of substances intended, through physiological action, for accelerating or retarding the rate of growth or rate of maturation, or for otherwise altering the behavior of plants,” while excluding plant nutrients, trace elements, nutritional chemicals, plant inoculants, and soil amendments, or fertilizers. See FIFRA sec. 2(v); 40 C.F.R. 152.6. There is no FIFRA exclusion for plant biostimulants as a general category of products; instead, when considering whether a particular plant biostimulant product may be subject to regulation under FIFRA as a PGR, EPA looks to both the claims made about the product as well as the product’s composition. This determination has significant implications, because if a product is classified as a PGR, it becomes subject to full regulatory oversight as a pesticide under FIFRA, and will require EPA pre-market approval (i.e., registration) before it may be distributed or sold in the United States.

In its newly revised draft guidance, EPA has attempted to further clarify these threshold definitional issues, even without presenting an official definition for plant biostimulants as a category of products. As with its initial draft, EPA provides lists of potential plant biostimulant claims that it has determined will not subject these products to FIFRA regulation, as well as those plant biostimulant product claims that will result in a product being considered “pesticidal”.

According to EPA, examples of “non-pesticidal” claims that do not trigger regulation as a PGR include:

- Avoids/corrects/prevents nutrition-based/nutrient deficiency-based plant disorders (e.g., including, but not limited to: blossom end rot, chlorosis, necrosis, discoloration, stunting, etc.)
- Improves soil/seed nutrient conditions for root growth
- Improve/increase/support biodegradation of organic matter
- Increases/improves/optimizes soil conditions for increased plant vigor
- Increases/improves/optimizes conditions for tolerance of/resistance to abiotic stress
- Improves overall plant nutrition
- Supports nutrient uptake

By contrast, examples of claims that demonstrate “pesticidal intent” and thus may trigger regulation as a PGR include:

- Enhances/promotes/stimulates fruit growth and development
- Inhibits/promotes sprouting
- Induce/promote/retard/suppress seed germination
- Enhances/promotes crop/fruit/produce color/development/quality/shape

In all cases, close evaluation of a specific product’s claims and composition will be required to determine its appropriate regulatory status.

Notable Changes from EPA’s 2019 Guidance

EPA made several significant changes to its initial draft guidance, including by:

- Clarifying that certain claims for increased or decreased plant growth, yield, or germination can be made without triggering pesticide regulation if they are *consequent to the intended use as an exception to the definition of a PGR* (for example, as a plant nutrient, inoculant, etc.). However, if the same claims are made

without qualification or specific reference to such an exception, they will be considered plant regulator claims and may subject the product to regulation as a pesticide.

- Narrowing and modifying the lists of substances that “have no other use than as plant regulators or pesticides” and substances which “have multiple plant regulator and non-plant regulator modes of action.” Commenters had recommended EPA remove these lists from the draft guidance altogether. While EPA retained this section in the guidance, the Agency significantly modified the lists of substances, while further clarifying which modes of action are indicative of plant growth regulation when a substance has multiple modes of action.

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